



Agricultural Marketing Service

7 CFR Part 205

[Document Number: AMS-NOP-19-0106; NOP-19-03]

RIN 0581-AD98

National Organic Program; National List of Allowed and Prohibited Substances (2022 Sunset).

AGENCY: Agricultural Marketing Service, USDA.

ACTION: Proposed rule.

SUMMARY: The U.S. Department of Agriculture's Agricultural Marketing Service proposes amendments to the National List of Allowed and Prohibited Substances (National List) section of the USDA's organic regulations to implement recommendations submitted to the Secretary of Agriculture (Secretary) by the National Organic Standards Board (NOSB). This rule proposes the removal from the National List of several substances currently allowed for various uses in organic crop production, livestock production, and manufacture of processed products.

DATES: Send comments on or before [INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER].

ADDRESSES: You may send comments on this proposed rule to the Federal eRulemaking Portal at <https://www.regulations.gov/>. You can access this proposed rule and instructions for submitting public comments by searching for document number AMS-NOP-19-0106. Comments may also be sent to Jared Clark, Standards Division, National Organic Program, USDA-AMS-NOP, 1400 Independence Ave. SW, Room 2642-So., Ag Stop 0268, Washington, DC 20250-0268.

Instructions: All comments received must include the docket number AMS-NOP-19-0106; NOP-19-03, and/or Regulatory Information Number (RIN) 0581-AD98 for this

rulemaking. You should clearly indicate the topic and section number of the proposed rule to which your comment refers, state your position(s), offer any recommended language change(s), and include relevant information and data to support your position(s) (e.g., scientific, environmental, manufacturing, industry, or industry impact information, etc.). All comments and relevant background documents posted to <https://www.regulations.gov> will include any personal information provided.

FOR FURTHER INFORMATION CONTACT: Jared Clark, Standards Division,
National Organic Program, Telephone: (202) 720-3252

SUPPLEMENTARY INFORMATION: In addition to comments about the proposed removals themselves, AMS is requesting comments about whether organic operations (producers and handlers) require time to implement the changes that would be necessary, should AMS finalize the amendments in this proposed rule. All of the substances/ingredients included in this rule have a “sunset date” of March 15, 2022, except for Turkish bay leaves and whey protein concentrate (sunset date of June 27, 2022). AMS requests comments on how much time after the sunset date is necessary, if any, for organic operations to comply with the proposed changes.

I. Background

On December 21, 2000, the Secretary established the Agricultural Marketing Service’s (AMS) National Organic Program and the USDA organic regulations (65 FR 80547). Within the USDA organic regulations (7 CFR part 205) is the National List of Allowed and Prohibited Substances (or “National List”). The National List identifies the synthetic substances that may be used and the nonsynthetic (natural) substances that may not be used in organic crop and livestock production. It also identifies the nonorganic substances that may be used in or on processed organic products (i.e., in organic “handling”).

To remain on the National List, substances must be: (1) reviewed every five years by the NOSB, a 15-member Federal advisory committee; and (2) renewed by the Secretary (7 U.S.C. 6517(e)). This action of NOSB review and USDA renewal is commonly referred to as the “sunset review” or “sunset process.” AMS published information about this process in the **Federal Register** on September 16, 2013 (78 FR 56811). The sunset date (i.e., the date by which the Secretary must renew a substance for the listing to remain valid on the National List) for each substance is included in the NOP Program Handbook (document NOP 5611).

Through the course of the sunset review process for the substances below, the NOSB determined the substances are no longer necessary for organic production or handling or otherwise no longer comply with the criteria set forth in the Organic Foods Production Act at 7 U.S.C. 6518.

Based on recommendations submitted at the conclusion of the NOSB’s sunset review process, AMS is proposing to amend the National List by removing the following synthetic substances currently allowed in organic crop and livestock production (7 CFR 205.601 and 205.603):

- Sucrose Octanoate Esters (crop production)
- Vitamin B₁ (crop production)
- Oxytocin (livestock production)
- Procaine (livestock production)
- Sucrose Octanoate Esters (livestock production)

Additionally, AMS is proposing to amend the National List by removing the following nonorganic ingredients currently allowed in organic handling (§§ 205.605 and 205.606):

- Alginic acid

- Colors (black currant juice color, blueberry juice color, carrot juice color, cherry juice color, grape juice color, paprika color, pumpkin juice color, turmeric extract color)
- Kelp
- Konjac flour
- Sweet potato starch
- Turkish bay leaves
- Whey protein concentrate

The proposed removal of these substances from the National List addresses National Organic Standards Board (NOSB) recommendations submitted to the Secretary after the conclusion of the NOSB's public meetings on October 29, 2015; November 2, 2017; October 26, 2018; and October 30, 2020.

II. Overview of Proposed Amendments

The following provides an overview of the proposed amendments to the National List, along with the NOSB and AMS justifications for each proposed amendment. AMS welcomes comments on the proposed amendments. Comments received during the comment period will inform AMS's decisions for the final rule – specifically, whether the proposed removals remain justified or new information demonstrates that renewal(s) (relisting) is warranted and aligned with OFPA criteria.

A. Sucrose Octanoate Esters (§§ 205.601 and 205.603)

AMS is proposing to remove sucrose octanoate esters from the National List. Sucrose octanoate esters were added to the National List effective December 11, 2007 (72 FR 69569), were renewed through two sunset reviews, and are currently listed at §§205.601(e)(10) and 205.603(b)(10). The 2007 rulemaking was initiated by an NOSB

recommendation in August 2005¹ for the addition of sucrose octanoate esters to the National List for use as an insecticide in organic crop production and as a miticide for use on honeybees.

Prior to the NOSB's 2018 Fall meeting, the NOSB received information indicating there are no current EPA registrations for sucrose octanoate esters and therefore no approved pesticide applications. Due to this information, as referenced in the published NOSB recommendations,²³ the Board voted to remove both the crop use listing (at § 205.601(e)(10)) and the livestock (honeybee) use (at § 205.603(b)(10)). The NOSB reasoned that no argument could be made that this substance remains an essential tool for organic production if there is no current legal use consistent with the National List restrictions.

AMS agrees with the NOSB recommendation to remove sucrose octanoate esters from the National List at §§ 205.601(e)(10) and 205.603(b)(10). By 2019, there were no EPA approved products with legal uses corresponding to the National List allowances. (83 FR 16087, 16088, 16094). EPA's April 13, 2018, notice shows that the registrant of sucrose octanoate esters (75197-1, 75197-2) voluntarily cancelled its registrations. Since 2018, EPA's Pesticide Product and Label System⁴ now shows two new registrations of sucrose octanoate esters (EPA Reg. No. 94424-1 and 94424-2, registered December 17, 2020), but no approved labels or uses are available at this time.

AMS agrees with the NOSB's recommendation to remove sucrose octanoate esters because this product's minimal commercial availability shows that sucrose octanoate esters are not essential for organic production. Public comments are requested

¹ NOSB August 17, 2005, Sucrose Octanoate Esters Recommendation:
<https://www.ams.usda.gov/sites/default/files/media/Sucrose%20Recommendation.pdf>

² NOSB Fall 2018 Crops Sunset Recommendations:
<https://www.ams.usda.gov/sites/default/files/media/CS2020SunsetFinalRecOct2018.pdf>

³ NOSB Fall 2018 Livestock Sunset Recommendations:
<https://www.ams.usda.gov/sites/default/files/media/LS2020SunsetFinalRecOct2018.pdf>

⁴ <https://iaspub.epa.gov/apex/pesticides/f?p=PPLS:1> accessed January 29, 2021

on whether there is additional information available regarding the need for this substance in organic production and the availability of sucrose octanoate esters given the recent registrations.

B. Vitamin B₁ (§ 205.601)

AMS is proposing to remove Vitamin B₁ from the National List. Vitamin B₁ was added to the National List at its inception on December 21, 2000 (65 FR 80547), was renewed through several sunset reviews, and is currently listed at § 205.601(j)(9) for use as a plant or soil amendment.

In support of their sunset review⁵, the NOSB requested a third-party technical report⁶ on vitamins B₁, C, and E, as they are used in crop production. The technical report found that the previous claims on root growth and reduction of transplant shock associated with vitamin B₁ were largely unsubstantiated outside of a laboratory environment. Due to this and the fact there was no support voiced during the public comment process regarding efficacy or necessity, the NOSB recommended removal, citing that given this new information they no longer find vitamin B₁ compatible with a system of organic agriculture per 7 U.S.C. 6518(m)(7).

AMS agrees with the NOSB recommendation to remove vitamin B₁ as a plant and soil amendment at § 205.601(j)(9). The information referenced in the NOSB recommendation regarding use and efficacy are compelling reasons to remove vitamin B₁ from the National List for organic crop production. Further, the 2015 technical report on vitamins for crop production identified several natural and nonsynthetic alternatives to vitamin B₁ including yeast, various meals (e.g. soybean meal, cottonseed meal), and other crop waste or residues. Accordingly, AMS proposes that vitamin B₁ is no longer

⁵ Formal Crops Sunset Recommendations from NOSB to NOP, November 2, 2017: <https://www.ams.usda.gov/sites/default/files/media/CS2019SunsetsFinalRec.pdf>

⁶ 2015 Technical Report on Vitamins B₁, C, and E used in crop production: <https://www.ams.usda.gov/sites/default/files/media/Vitamins%20B1-C-E%20TR%202015.pdf>

necessary to the production of agricultural product and should be removed from the National List due to the availability of wholly natural substitutes (7 U.S.C. 6517(c)(1)(A)(ii)).

C. Oxytocin (§ 205.603)

AMS is proposing to remove oxytocin from the National List. Oxytocin was added to the National List at its inception on December 21, 2000 (65 FR 80547), was renewed through several sunset reviews, and is currently listed at § 205.603(a)(22) for use in post parturition therapeutic applications.

In the sunset review, the NOSB recommended⁷ the removal of oxytocin from the National List. The NOSB determined that there are now numerous alternative methods and materials for addressing the health issues where oxytocin would be used and that the use of oxytocin no longer meets the criteria at 7 U.S.C. 6518(m)(6). Additionally, the NOSB found that use of oxytocin is not compatible with a system of sustainable agriculture (7 U.S.C. 6518(m)(7)). The NOSB requested public comment on whether this substance is essential for organic production or if there are alternative materials and methods that render it unnecessary. The public comment received in response to the request indicated that this substance is no longer necessary and supported its removal.

AMS tentatively agrees with the NOSB recommendation. While the NOSB states there are other practices or materials that render oxytocin unnecessary for organic production, AMS did not find supporting comments to that effect, and NOSB did not specifically state what the alternatives are. Further, it was stated in public comment to the NOSB that while some operations still use oxytocin as a medical treatment (assisting in clearing placenta), other operations may be using it in ways inconsistent with the listing or no longer find it necessary in organic production. AMS is seeking comments on

⁷ Formal Livestock Sunset Recommendations from NOSB to NOP, November 2, 2017: <https://www.ams.usda.gov/sites/default/files/media/LS2019SunsetsFinalRec.pdf>

whether suitable alternatives for the use of oxytocin exist, and if so, specifically what alternative practices or materials might replace the use of oxytocin. Further, AMS seeks information on oxytocin use that may be inconsistent with the listing. If comments show that the use of oxytocin no longer meets the exemption requirements at 7 U.S.C. 6517(c)(1)(A)(ii) and (iii), AMS is proposing the removal of oxytocin from the National List at § 205.603(a)(22).

D. Procaine (§ 205.603)

AMS is proposing to remove procaine from the National List. Procaine was added to the National List at its inception on December 21, 2000 (65 FR 80547), was renewed through several sunset reviews, and is currently listed at § 205.603(b)(8) for use as a local anesthetic.

In support of the NOSB's sunset review of procaine, public comment was requested to determine if procaine is used in organic livestock production and whether procaine is only available in the U.S. in animal drugs compounded with antibiotics (which are not permitted in organic production) or whether procaine can be sourced by itself. The comments received indicated that procaine is rarely used, is not as effective as lidocaine (allowed in organic livestock production at § 205.603(b)(5)), and is only available in combination with prohibited antibiotics. Further comments received were in support of removing procaine from the National List. Based on the information received during the public comment period, the NOSB recommended⁸ removal of procaine, given that it no longer meets the criteria stipulated by OFPA at 7 U.S.C. 6518(m)(6), due to lidocaine being more effective and because procaine is not available (i.e., compounded without prohibited antibiotics).

⁸ Formal Livestock Sunset Recommendations from NOSB to NOP, November 2, 2017: <https://www.ams.usda.gov/sites/default/files/media/LS2019SunsetsFinalRec.pdf>

AMS agrees with the NOSB recommendation. Given that there is another National List material, lidocaine, that renders procaine unnecessary for organic production, procaine no longer meets the exemption requirement at 7 U.S.C. 6517(c)(1)(A)(ii). Further, the NOSB referenced in their recommendation that procaine is not available on its own (i.e., not compounded with an antibiotic). A search of the FDA's animal drug database (<https://animaldrugsatfda.fda.gov/>) indicates that all sixteen of the FDA approved drugs that contain procaine also contain an antibiotic (e.g., Penicillin G Procaine). This information supports the fact that procaine is not used in organic production and that an exemption is not necessary (7 U.S.C. 6517(c)(1)(A)(ii)). As procaine no longer appears to meet the requirements for inclusion on the National List, AMS is proposing the removal of procaine from the National List at § 205.603(b)(8).

E. Alginic Acid (§ 205.605)

AMS is proposing to remove alginic acid from the National List. Alginic acid was added to § 205.605(a) of the National List at its inception on December 21, 2000 (65 FR 80547), was renewed through several sunset reviews, and was reclassified as synthetic on December 27, 2018 (83 FR 66559), which moved alginic acid to its current listing at § 205.605(b) for use in organic handling.

In support of their sunset review of alginic acid, the NOSB received a third-party technical report⁹ in 2015 and solicited public comment at their Spring 2019 meeting. The NOSB received no comments in support of continuing the allowance or reporting use of alginic acid. In addition, no certifying agents (“certifiers”) reported this material being used by their certified operations. Further, the 2015 technical report cited other National List materials, including agar-agar, carrageenan, gellan gum, and xanthan gum, as possible alternatives to alginic acid. Based on this, the NOSB determined that there are

⁹ Alginic Acid Technical Report, February 5, 2015:
<https://www.ams.usda.gov/sites/default/files/media/Alginic%20Acid%20TR.pdf>

readily available alternatives and recommended removal based on alginic acid no longer meeting the OFPA criteria at 7 U.S.C. 6518(m)(6).

AMS agrees with the NOSB recommendation. Given that there were no reports of operations using alginic acid and the availability of possible alternatives on the National List (as referenced in the technical report), this substance no longer appears to meet the requirements for inclusion on the National List at 7 U.S.C. 6517(c)(1)(A)(ii). As such, AMS proposes the removal of alginic acid from the National List at § 205.605(b).

F. Colors (§ 205.606)

AMS is proposing to remove eight nonorganic colors from the National List at § 205.606(d):

- Black currant juice color - derived from *Ribes nigrum* L.
- Blueberry juice color - derived from blueberries (*Vaccinium spp.*).
- Carrot juice color - derived from *Daucus carota* L.
- Cherry juice color - derived from *Prunus avium* (L.) L. or *Prunus cerasus* L.
- Grape juice color - derived from *Vitis vinifera* L.
- Paprika color - derived from dried powder or vegetable oil extract of *Capsicum annuum* L.
- Pumpkin juice color - derived from *Cucurbita pepo* L. or *Cucurbita maxima* Duchesne.
- Turmeric extract color - derived from *Curcuma longa* L.

These colors were added to the National List effective June 21, 2007 (72 FR 35137), were renewed through several sunset reviews, and are currently listed at § 205.606(d) as allowed nonorganic agricultural ingredients in organic products when organic versions are not commercially available.

The NOSB recommended¹⁰ the removal of the above colors at their Fall 2020 meeting. The effect of this action is that only organic forms of these colors would be allowed in organic handling. The NOSB referenced public comments as being mixed on the availability and necessity of these colors and also noted that comments from some manufacturers stated that organic versions of these colors are available. Additionally, in the case of carrot juice color and grape juice color, the NOSB noted that the availability of these crops in organic forms should provide an adequate supply of organic carrot juice and organic grape juice for color production and cited that as a reason for their recommended removal.

AMS is proposing to remove these colors from the National List, as recommended by the NOSB. AMS is seeking comments about whether these colors remain necessary for organic production or if there are suitable organic versions available. While public comments to the NOSB were mixed, as noted in the NOSB recommendation, most of the comments were in favor of relisting these colors. Because these colors are listed in § 205.606, certified operations are required to use organic versions of these colors unless the organic versions are not commercially available (i.e., not available in an appropriate form, quality, or quantity). Many of the comments supporting relisting were from organic handlers claiming that while one or more of these colors are available in organic form, they are not available in the same form or quality as the nonorganic version. Some comments from color manufacturers, however, stated that they have sufficient quantity of these colors in organic form.

AMS welcomes public comments that provide more information on whether there are sufficient amounts of the organic versions of the above colors to meet demand and on the availability of organic colors in suitable form and quality. If any of these colors are

¹⁰ Formal Handling Sunset Recommendations from the NOSB to the NOP, October 30, 2020: https://www.ams.usda.gov/sites/default/files/media/HS2022SunsetRecs_webpost.pdf

still necessary in their nonorganic form, comments should provide specific information on the attributes of the nonorganic form that are not yet sufficiently available in the organic forms. If any or all of the above colors are not currently commercially available in organic form, we request comment on whether they should be relisted (i.e. not removed in the final rule) or whether the final rule should provide an implementation period to provide time for sufficient quantity, quality, and/or form of the color(s) to be developed.

G. Kelp (§ 205.606)

AMS is proposing to remove nonorganic kelp from the National List. The effect of this action is that only organic forms of kelp would be allowed in organic handling. Kelp was added to the National List at its inception on December 21, 2000 (65 FR 80547), was renewed through several sunset reviews, and is currently listed at § 205.606(k) for use only as a thickener and dietary supplement only when an organic version is not commercially available.

After the Fall 2020 meeting, the NOSB recommended¹¹ the removal of kelp from the National List at § 205.606. During this sunset review, the NOSB received comments in support of removing as well as relisting kelp. In this sunset review, the NOSB determined that there were alternatives to kelp on the National List (namely kombu and wakame), which rendered the kelp listing no longer necessary. Because kelp no longer meets the requirement of OFPA at 7 U.S.C. 6518(m)(6) due to the existence of alternatives, the NOSB voted to recommend the removal of kelp from the National List at § 205.606.

AMS agrees with the NOSB recommendation. According to the Organic Integrity Database¹², there are currently 106 certified crop, wild crop, and handling operations that

¹¹ Formal Handling Sunset Recommendations from the NOSB to the NOP, October 30, 2020: https://www.ams.usda.gov/sites/default/files/media/HS2022SunsetRecs_webpost.pdf

¹² Organic Integrity Database, accessed February 12, 2021:

list “kelp” as a certified organic product. Organic kelp appears to be commercially available; therefore, this substance no longer appears to be necessary and no longer meets the requirements for inclusion on the National List at 7 U.S.C. 6517(c)(1)(A)(ii). As such, AMS proposes the removal of nonorganic kelp from the National List at § 205.606(k).

H. Konjac Flour (§ 205.606)

AMS is proposing to remove nonorganic konjac flour from the National List. The effect of this action is that only organic forms of konjac flour would be allowed in organic handling. Konjac flour was added to the National List effective June 21, 2007 (72 FR 35137), renewed through two sunset reviews, and is currently listed at § 205.606(l). The 2007 rulemaking was initiated by an NOSB recommendation¹³ for the addition of konjac flour to the National List only when an organic version is not commercially available.

After the Fall 2017 meeting, the NOSB recommended¹⁴ the removal of konjac flour. In support of their recommendation, the NOSB solicited public comment regarding the use and necessity of konjac flour in organic handling and the availability of organic konjac flour. The NOSB received little feedback from industry in response. One trade organization reported one organic producer using konjac flour but was unsure if it was for organic products. Several certifiers stated they had not received any feedback from their clients regarding the need for or use of nonorganic konjac flour in their products. Ultimately, the NOSB voted to recommend removal of konjac flour from the National List at § 205.606(l) due to the availability of alternatives, as well as the fact that nonorganic konjac flour no longer meets the OFPA requirements at 7 U.S.C. 6518(m)(6).

<https://organic.ams.usda.gov/integrity/Search.aspx>

¹³ NOSB Meeting Minutes & Transcripts 1992-2009:

<https://www.ams.usda.gov/sites/default/files/media/NOSB%20Meeting%20Minutes%26Transcripts%201992-2009.pdf>

¹⁴ NOSB Formal Handling Sunset Recommendations, November 2, 2017:

<https://www.ams.usda.gov/sites/default/files/media/HS2019SunsetsFinalRec.pdf>

AMS agrees with the NOSB recommendation. A search in the Organic Integrity Database¹⁵ for “konjac” shows 30 operations with some form of certified organic konjac products (e.g., powder, starch, konjac tubers). Given the lack of reported use of, or need for, nonorganic konjac flour and the availability of organic konjac flour and konjac tubers, nonorganic konjac flour appears to no longer meet the requirements for inclusion on the National List at 7 U.S.C. 6517(c)(1)(A)(ii). As such, AMS proposes the removal of nonorganic konjac flour from the National List at § 205.606(l).

I. Sweet Potato Starch (§ 205.606)

AMS is proposing to remove nonorganic sweet potato starch from the National List. The effect of this action is that only organic forms of sweet potato starch would be allowed in organic handling. Sweet potato starch was added to the National List effective June 21, 2007 (72 FR 35137), was renewed through two sunset reviews, and is currently listed at § 205.606(s)(2). The 2007 rulemaking was initiated by an NOSB recommendation¹⁶ for the allowance of nonorganic sweet potato starch for bean thread production only when an organic version is not commercially available.

After the Fall 2020 meeting, the NOSB recommended¹⁷ the removal of sweet potato starch from the National List at § 205.606. NOSB solicited comment on the use and necessity of sweet potato starch and received little feedback. The comments that were received suggested scant use of nonorganic sweet potato starch, readily available alternatives, and the availability of organic forms of sweet potato starch. Further, comments noted that the continued listing of nonorganic sweet potato starch is inhibiting increased production of organic forms of sweet potato starch. Based on this information,

¹⁵ USDA Organic Integrity Database, accessed February 12, 2021:

<https://organic.ams.usda.gov/integrity/default.aspx>

¹⁶ NOSB Meeting Minutes & Transcripts 1992-2009:

<https://www.ams.usda.gov/sites/default/files/media/NOSB%20Meeting%20Minutes%26Transcripts%201992-2009.pdf>

¹⁷ Formal Handling Sunset Recommendations from the NOSB to the NOP, October 30, 2020:

https://www.ams.usda.gov/sites/default/files/media/HS2022SunsetRecs_webpost.pdf

the NOSB determined that there are available alternatives to nonorganic sweet potato starch and recommended the removal of this substance because its use no longer meets the OFPA criteria at 7 U.S.C. 6518(m)(6).

AMS agrees with the NOSB recommendation. A search in the Organic Integrity Database¹⁸ for “potato starch” shows 54 operations with some form of certified organic potato starch and another 25 operations with some form of certified organic pea starch, a cited alternative to sweet potato starch. Given the low reported use of nonorganic sweet potato starch and the availability of organic sweet potato starch and pea starch, nonorganic sweet potato starch appears to no longer meet the requirements for inclusion on the National List at 7 U.S.C. 6517(c)(1)(A)(ii). As such, AMS proposes the removal of nonorganic sweet potato starch from the National List at § 205.606(s)(2).

J. Turkish bay leaves (§ 205.606)

AMS is proposing to remove nonorganic Turkish bay leaves from the National List. The effect of this action is that organic forms only of Turkish bay leaves would be allowed in organic handling. Turkish bay leaves were added to the National List effective June 21, 2007 (72 FR 35137), were renewed through two sunset reviews, and are currently listed at § 205.606(v). The 2007 rulemaking was initiated by an NOSB recommendation¹⁹ for the addition of Turkish bay leaves to the National List for use in organic production only when organic versions are not commercially available.

After the Fall 2015 meeting, the NOSB recommended²⁰ removal of Turkish bay leaves from § 205.606. This recommendation was not finalized by AMS (82 FR 31241) because public comments requested AMS maintain the allowance. Comments reported

¹⁸ USDA Organic Integrity Database, accessed February 8, 2021:

<https://organic.ams.usda.gov/integrity/default.aspx>

¹⁹ NOSB Meeting Minutes & Transcripts 1992-2009:

<https://www.ams.usda.gov/sites/default/files/media/NOSB%20Meeting%20Minutes%26Transcripts%201992-2009.pdf>

²⁰ Formal Handling Sunset Recommendation from the NOSB to the NOP, October 2015:

https://www.ams.usda.gov/sites/default/files/media/HS%202017%20Sunset%20Final%20Rvw%20605%28a%29_%28b%29_606_final%20rec.pdf

that organic whole Turkish bay leaves were not available in the quantity or quality to meet organic handling needs. During the 2020 sunset review, the NOSB received many comments supporting the removal of Turkish bay leaves due to the availability of organic versions. The NOSB cited one commenter, who uses Turkish bay leaves in a wide range of canned soups and stated there is full availability of organic forms of Turkish bay leaves. Further comments from certifiers indicated that few, if any, of their operations use nonorganic Turkish bay leaves. Based on this information, the NOSB determined that there are available alternatives to nonorganic Turkish bay leaves and recommended²¹ the removal of this substance because it no longer meets the OFPA criteria at 7 U.S.C. 6518(m)(6).

AMS agrees with the NOSB recommendation. A search in the Organic Integrity Database²² for “bay leaves” shows 100 crop and handling operations with some form of certified organic bay leaves. A search using the term “Turkish bay leaves” shows five operations, as it appears that only one certifier identifies bay leaves with that level of specificity in the Organic Integrity Database. Given that comments to the NOSB indicated organic Turkish bay leaves are readily available in all forms and the high number of operations reported in the Organic Integrity Database with organic bay leaves (of which a subset are Turkish bay leaves), nonorganic Turkish bay leaves appear to no longer meet the requirements for inclusion on the National List at 7 U.S.C. 6517(c)(1)(A)(ii). As such, AMS proposes the removal of nonorganic Turkish bay leaves from the National List at § 205.606(v).

K. Whey protein concentrate (§ 205.606)

²¹ Formal Handling Sunset Recommendations from the NOSB to the NOP, October 30, 2020: https://www.ams.usda.gov/sites/default/files/media/HS2022SunsetRecs_webpost.pdf

²² USDA Organic Integrity Database, accessed February 8, 2021: <https://organic.ams.usda.gov/integrity/default.aspx>

AMS is proposing to remove nonorganic whey protein concentrate from the National List. The effect of this action is that only organic forms of whey protein concentrate would be allowed in organic handling. Whey protein concentrate was added to the National List effective June 21, 2007 (72 FR 35137), was renewed through two sunset reviews, and is currently listed at § 205.606(x). The 2007 rulemaking was initiated by an NOSB recommendation made at the March 2007²³ NOSB meeting for the addition of whey protein concentrate to the National List for organic production only when an organic version is not commercially available.

After the Fall 2015 meeting, the NOSB recommended²⁴ removal of whey protein concentrate from § 205.606. This recommendation was not finalized by AMS (82 FR 31243) because public comment asserted that whey protein concentrate was essential to organic processed products, and there was no commercially available organic product. During the 2020 sunset review, the NOSB received many comments supporting the removal of whey protein concentrate due to the availability of organic versions. The NOSB cited several commenters who demonstrated that they produce a robust supply of organic whey protein concentrate in several forms and sell excess to the conventional market. A comment noted that the international supply chain of organic whey-based products is also robust. Further comment from at least one certifier indicated that none of their operations are using nonorganic whey protein concentrate. Based on this information, the NOSB determined that there are available alternatives to nonorganic whey protein concentrate and recommended²⁵ the removal of this substance because it no longer meets the OFPA criteria at 7 U.S.C. 6518(m)(6).

²³ NOSB Meeting Minutes & Transcripts 1992-2009:
<https://www.ams.usda.gov/sites/default/files/media/NOSB%20Meeting%20Minutes%26Transcripts%201992-2009.pdf>

²⁴ Formal Handling Sunset Recommendation from the NOSB to the NOP, October 2015:
https://www.ams.usda.gov/sites/default/files/media/HS%202017%20Sunset%20Final%20Rvw%20605%28a%29_%28b%29_606_final%20rec.pdf

²⁵ Formal Handling Sunset Recommendations from the NOSB to the NOP, October 30, 2020:
https://www.ams.usda.gov/sites/default/files/media/HS2022SunsetRecs_webpost.pdf

AMS agrees with the NOSB recommendation. A search in the Organic Integrity Database²⁶ for “whey protein concentrate” shows 22 operations with some form of certified organic whey protein concentrate. The NOSB also received comments stating that there is a substantial supply of all forms of organic whey protein concentrate and cited the diversion of some quantity to the conventional market as evidence that there is enough supply to meet the demand for organic whey protein concentrate. Given the comments submitted to the NOSB outlining the lack of use and stated abundance of supply, nonorganic whey protein concentrate appears to no longer meet the requirements for inclusion on the National List at 7 U.S.C. 6517(c)(1)(A)(ii). As such, AMS proposes the removal of nonorganic whey protein concentrate from the National List at § 205.606(x).

III. Statutory and Regulatory Authority

The OFPA authorizes the Secretary to make amendments to the National List based on recommendations developed by the NOSB. Sections 6518(k) and 6518(n) of the OFPA authorize the NOSB to develop recommendations for submission to the Secretary to amend the National List and establish a process by which persons may petition the NOSB for the purpose of having substances evaluated for inclusion on or deletion from the National List. Section 205.607 of the USDA organic regulations permits any person to petition to add or remove a substance from the National List and directs petitioners to obtain the petition procedures from USDA. The current petition procedures published in the **Federal Register** (81 FR 12680, March 10, 2016) for amending the National List can be accessed through the NOP Program Handbook on the NOP Web site at https://www.ams.usda.gov/rules-regulations/organic/handbook_

A. Executive Orders 12866 and 13563 and the Regulatory Flexibility Act

²⁶ USDA Organic Integrity Database, accessed February 8, 2021: <https://organic.ams.usda.gov/integrity/default.aspx>

This proposed rule does not meet the criteria of a significant regulatory action under Executive Order 12866 as supplemented by Executive Order 13563. Therefore, the Office of Management and Budget (OMB) has not reviewed this rule under those Orders.

The Regulatory Flexibility Act (RFA) (5 U.S.C. 601–612) requires agencies to consider the economic impact of each rule on small entities and evaluate alternatives that would accomplish the objectives of the rule without unduly burdening small entities or erecting barriers that would restrict their ability to compete in the market. The purpose of the RFA is to fit regulatory actions to the scale of businesses subject to the action.

The Small Business Administration (SBA) sets size criteria for each industry described in the North American Industry Classification System (NAICS) to delineate which operations qualify as small businesses. The SBA has classified small agricultural producers that engage in crop and animal production as those with average annual receipts of less than \$1,000,000. Handlers are involved in a broad spectrum of food production activities and fall into various categories in the NAICS Food Manufacturing sector. The small business thresholds for food manufacturing operations are based on the number of employees and range from 500 to 1,250 employees, depending on the specific type of manufacturing. Certifying agents fall under the NAICS subsector “All other professional, scientific and technical services.” For this category, the small business threshold is average annual receipts of less than \$16.5 million.

AMS has considered the economic impact of this proposed rulemaking on small agricultural entities. Data collected by the USDA National Agricultural Statistics Service (NASS) and the NOP indicate most of the certified organic production operations in the United States would be considered small entities. According to the 2019 Census of Agriculture, 16,585 organic farms in the United States reported sales of organic products and total farmgate sales more than \$9.9 billion.²⁷ Based on that data, organic sales

²⁷ U.S. Department of Agriculture, National Agricultural Statistics Service. 2019 Census of Agriculture.

average just under \$600,000 per farm. Assuming a normal distribution of producers, we expect that most of these producers would fall under the \$750,000 sales threshold to qualify as a small business.

According to the NOP's Organic Integrity Database, there are 19,059 organic handlers that are certified under the USDA organic regulations.²⁸ The Organic Trade Association's 2020 Organic Industry Survey has information about employment trends among organic manufacturers. The reported data are stratified into three groups by the number of employees per company: less than 5; 5 to 49; and 50 plus. These data are representative of the organic manufacturing sector and the lower bound (50) of the range for the larger manufacturers is significantly smaller than the SBA's small business thresholds (500 to 1,250). Therefore, AMS expects that most organic handlers would qualify as small businesses.

SBA defines small agricultural service firms, which include certifying agents, as those having annual receipts of less than \$8,000,000 (13 CFR 121.201). There are currently 77 USDA-accredited certifying agents; based on a query of the NOP certified organic operations database. While many certifying agents are small entities that would be affected by this proposed rule, we do not expect that these certifying agents would incur significant costs as a result of this action. Certifying agents already must comply with the current regulations, e.g., maintaining certification records for organic operations.

AMS has determined that this rule would not have a significant impact on a substantial number of small entities, as defined by SBA. The effect of this rule, if implemented as final, would be to remove the allowance of seventeen substances in organic production and organic handling. The removal of these substances, while numerous, is due to the fact that alternatives have rendered them no longer necessary,

https://www.nass.usda.gov/Publications/AgCensus/2017/Online_Resources/Organics/ORGANICS.pdf

²⁸ Organic Integrity Database: <https://organic.ams.usda.gov/Integrity/>. Accessed on January 29, 2021.

they are no longer in use, or organic versions have become available. AMS invites comments on the anticipated costs of this proposed rule, including the impacts on small businesses.

B. Executive Order 12988

Executive Order 12988 instructs each executive agency to adhere to certain requirements in the development of new and revised regulations to avoid unduly burdening the court system. Accordingly, to prevent duplicative regulation, states and local jurisdictions are preempted under the OFPA from creating programs of accreditation for private persons or state officials who want to become certifying agents of organic farms or handling operations. A governing state official would have to apply to USDA to be accredited as a certifying agent, as described in section 6514(b) of the OFPA. States are also preempted under sections 6503 through 6507 of the OFPA from creating certification programs to certify organic farms or handling operations unless the state programs have been submitted to, and approved by, the Secretary as meeting the requirements of the OFPA.

Pursuant to section 6507(b)(2) of the OFPA, a state organic certification program that has been approved by the Secretary may, under certain circumstances, contain additional requirements for the production and handling of agricultural products organically produced in the state and for the certification of organic farm and handling operations located within the state. Such additional requirements must (a) further the purposes of the OFPA, (b) not be inconsistent with the OFPA, (c) not be discriminatory toward agricultural commodities organically produced in other States, and (d) not be effective until approved by the Secretary.

In addition, pursuant to section 6519(c)(6) of the OFPA, this proposed rule would not supersede or alter the authority of the Secretary under the Federal Meat Inspection Act (21 U.S.C. 601–624), the Poultry Products Inspection Act (21 U.S.C. 451–471), or

the Egg Products Inspection Act (21 U.S.C. 1031–1056), concerning meat, poultry, and egg products, respectively, nor any of the authorities of the Secretary of Health and Human Services under the Federal Food, Drug and Cosmetic Act (21 U.S.C. 301 *et seq.*), nor the authority of the Administrator of the EPA under the Federal Insecticide, Fungicide and Rodenticide Act (7 U.S.C. 136 *et seq.*).

This proposed rule is not intended to have a retroactive effect.

C. Paperwork Reduction Act

No additional collection or recordkeeping requirements are imposed on the public by this proposed rule. Accordingly, OMB clearance is not required by the Paperwork Reduction Act of 1995, 44 U.S.C. 3501, Chapter 35.

D. Executive Order 13175

This proposed rule has been reviewed under Executive Order 13175 – Consultation and Coordination with Indian Tribal Governments. Executive Order 13175 requires Federal agencies to consult and coordinate with tribes on a government-to-government basis on: (1) policies that have tribal implication, including regulation, legislative comments, or proposed legislation; and (2) other policy statements or actions that have substantial direct effects on one or more Indian tribes, on the relationship between the Federal Government and Indian tribes, or on the distribution of power and responsibilities between the Federal Government and Indian tribes.

AMS has assessed the impact of this proposed rule on Indian tribes and determined that this rule would not have tribal implications that require consultation under Executive Order 13175. AMS hosts a quarterly teleconference with tribal leaders where matters of mutual interest regarding the marketing of agricultural products are discussed. Information about the proposed changes to the regulations will be shared during an upcoming quarterly call, and tribal leaders will be informed about the proposed revisions to the regulation and the opportunity to submit comments. AMS will work with

the USDA Office of Tribal Relations to ensure meaningful consultation is provided as needed with regards to the NOP regulations.

E. General Notice of Public Rulemaking

This proposed rule reflects recommendations submitted by the NOSB to the Secretary to add three substances to the National List. A 60-day period for interested persons to comment on this rule is provided.

List of Subjects in 7 CFR Part 205

Administrative practice and procedure, Agriculture, Animals, Animal drugs, Dairy products, Food grades and standards, Foods, Labeling, Livestock, Meat and meat products, Organically produced products, Reporting and recordkeeping requirements, Seals and insignia.

For the reasons set forth in the preamble, AMS proposes to amend 7 CFR part 205 as follows:

PART 205—NATIONAL ORGANIC PROGRAM

1. The authority citation for 7 CFR part 205 continues to read as follows:

Authority: 7 U.S.C. 6501-6524.

2. Amend § 205.601 by removing paragraph (e)(10) and revising paragraph (j)(9).

The revision to read as follows:

§ 205.601 Synthetic substances allowed for use in organic crop production.

* * * * *

(j) * * *

(9) Vitamins C and E.

* * * * *

§ 205.603 [Amended]

3. Amend § 205.603 by:

a. Removing paragraph (a)(22);

- b. Redesignating paragraphs (a)(23) through (30) as paragraphs (a)(22) through (29), respectively;
- c. Removing paragraphs (b)(8) and (10); and
- d. Redesignating paragraphs (b)(9), (11) and (12) as paragraphs (b)(8) through (10), respectively.

§ 205.605 [Amended]

- 4. In § 205.605(b) remove the words “Alginic acid (CAS #9005-32-7)”.
- 5. Revise § 205.606 to read as follows:

§ 205.606 Nonorganically produced agricultural products allowed as ingredients in or on processed products labeled as “organic.”

Only the following nonorganically produced agricultural products may be used as ingredients in or on processed products labeled as “organic,” only in accordance with any restrictions specified in this section, and only when the product is not commercially available in organic form.

- (a) Carnauba wax
- (b) Casings, from processed intestines.
- (c) Celery powder.
- (d) Colors derived from agricultural products—Must not be produced using synthetic solvents and carrier systems or any artificial preservative.
 - (1) Beet juice extract color—derived from *Beta vulgaris* L., except must not be produced from sugarbeets.
 - (2) Beta-carotene extract color—derived from carrots (*Daucus carota* L.) or algae (*Dunaliella salina*).
 - (3) Black/purple carrot juice color—derived from *Daucus carota* L.
 - (4) Chokeberry, aronia juice color—derived from *Aronia arbutifolia* (L.) Pers. or *Aronia melanocarpa* (Michx.) Elliott.

- (5) Elderberry juice color—derived from *Sambucus nigra* L.
- (6) Grape skin extract color—derived from *Vitis vinifera* L.
- (7) Purple sweet potato juice color—derived from *Ipomoea batatas* L. or *Solanum tuberosum* L.
- (8) Red cabbage extract color—derived from *Brassica oleracea* L.
- (9) Red radish extract color—derived from *Raphanus sativus* L.
- (10) Saffron extract color—derived from *Crocus sativus* L.
- (e) Fish oil (Fatty acid CAS #'s: 10417-94-4, and 25167-62-8)—stabilized with organic ingredients or only with ingredients on the National List, §§205.605 and 205.606.
- (f) Fructooligosaccharides (CAS # 308066-66-2).
- (g) Gelatin (CAS # 9000-70-8).
- (h) Glycerin (CAS # 56-81-5)—produced from agricultural source materials and processed using biological or mechanical/physical methods as described under § 205.270(a).
- (i) Gums—water extracted only (Arabic; Guar; Locust bean; and Carob bean).
- (j) Inulin-oligofructose enriched (CAS # 9005-80-5).
- (k) Lecithin—de-oiled.
- (l) Orange pulp, dried.
- (m) Orange shellac-unbleached (CAS # 9000-59-3).
- (n) Pectin (non-amidated forms only).
- (o) Potassium acid tartrate.
- (p) Seaweed, Pacific kombu.
- (q) Starches.
 - (1) Cornstarch (native).
 - (2) [Reserved]
- (r) Tamarind seed gum.

(s) Tragacanth gum (CAS #-9000-65-1).

(t) Wakame seaweed (*Undaria pinnatifida*).

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